IN THE UNITED STATES DISTRICT COURT FOR THE

WESTERN DISTRICT OF OKLAHOMA

LINDA INGRAM, Individually and as Surviving Spouse of RICK INGRAM, Deceased,	)	
Plaintiff,	)	
v.	)	Case No. CIV-05-913-L
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant.	)	

O R D E R

This is a pharmaceutical products liability lawsuit involving the Novartis Pharmaceuticals Corporation ("NPC") drugs Aredia and Zometa. Aredia and Zometa are bisphosphonates prescribed to patients with multiple myeloma, hypercalcemia of malignancy, or certain kinds of cancer that has metastasized to the bones. Plaintiff Linda Ingram, as the personal representative of her deceased husband Rick Ingram's estate, brings this suit alleging claims for strict liability and negligence. Complaint, Doc. No. 1. This case was consolidated with similar cases in a multi-district litigation ("MDL") proceeding in the Middle District of Tennessee, and was remanded to this court for further proceedings on August 23, 2011. Doc. No. 37.

In January 1999, Mr. Ingram was diagnosed with multiple myeloma. He was prescribed Aredia in January 1999 and received it until January 2003, when

he was switched to Zometa. He received Zometa until February 2004. Both medications were prescribed to treat Mr. Ingram's bone pain and decrease his risk for skeletal-related events. Mr. Ingram passed away in July of 2004. Joint Status Report, Doc. No. 43.

Plaintiff alleges that, as a result of taking these medications, Mr. Ingram developed osteonecrosis of the jaw ("ONJ"). Plaintiff alleges that NPC knew or should have known of the risk of ONJ from the use of Aredia and Zometa prior to January, 1999, but failed to provide a different or earlier warning. Plaintiff claims that Mr. Ingram would not have developed ONJ had NPC provided an adequate warning about the risks of Aredia and Zometa. Id.

This matter is before the court on NPC's Motion for Summary Judgment [Doc. No. 81]. Summary judgment is appropriate when the pleadings and supporting documents, viewed in the light most favorable to the nonmoving party, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986); Fed. R. Civ. P. 56(a) ("[T]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."). Substantive law determines which facts are material. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The dispute must be genuine, that is, "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id.

The party opposing summary judgment may not rest upon the mere allegations or denials of the party's pleadings, but must set forth specific facts showing that there is a genuine issue for trial. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986); Fed. R. Civ. P. 56(e)(3) ("If a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact as required by Rule 56(c), the court may . . . grant summary judgment if the motion and supporting materials – including the facts considered undisputed – show that the movant is entitled to it[.]"). The mere possibility that a factual dispute may exist, without more, is not sufficient to overcome a convincing presentation by the moving party. Allegations alone will not defeat summary judgment. Cone v. Longmont United Hosp. Ass'n., 14 F.3d 526, 530 (10th Cir. 1994). Any doubt as to the existence of a genuine issue of material fact must be resolved against the party seeking summary judgment. In addition, the inferences drawn from the facts presented must be construed in the light most favorable to the nonmoving party. Board of Education v. Pico, 457 U.S. 853, 863 (1982).

To prevail on her claims, plaintiff must establish both that (1) Aredia and/or Zometa in fact caused Mr. Ingram's injury and (2) that NPC's failure to warn was the proximate cause of his injury. Eck v. Parke, Davis & Co., 256 F. 3d 1013, 1017 (10th Cir. 2001). Under Oklahoma law, a manufacturer of a prescription drug is required to warn not the ultimate consumer, but the prescribing physician,

under the learned intermediary doctrine. Id. Even if the plaintiff establishes a duty to warn and a breach of that duty, she "must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided." Id. at 1018 (citations omitted). As stated by this court in Stafford v. Wyeth, 411 F. Supp.2d 1318, 1320 (W.D. Okla. 2006), with respect to prescription drugs, Oklahoma' learned intermediary doctrine provides that:

> Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprize the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.
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> Id., *citing* Edwards v. Basel Pharms., 933 P.2d 298, 300-01 (Okla. 1997) (*quoting* Wooderson v. Ortho Pharm. Corp., 235 Kan. 387, 681 P.2d 1038, 1052, *cert. denied*, 469 U.S. 965, 105 S.Ct. 365, 83 L.Ed.2d 301 (1984)).

Oklahoma's heeding presumption is that a prescribing physician given an adequate warning would have "heeded" the warning by incorporating that warning into his risk-benefit analysis in deciding whether to prescribe a given drug. Eck, 256 F.3d at

1021. This does *not* create a presumption that the drug would not have been prescribed, as plaintiff suggests, but rather assumes that the treating physician will incorporate the warnings into the risk/benefit analysis in deciding whether to prescribe a given drug. *See* Stafford, 411 F. Supp. 2d at 1322.

Plaintiff is therefore entitled to a rebuttable presumption that Mr. Ingram's prescribing physician would have read and heeded an adequate warning had one been given. Stafford, 411 F. Supp.2d at 1320 (*citing* Eck, 256 F.3d at 1018). For purposes of ruling on NPC's Motion for Summary Judgment, the court assumes without deciding that plaintiff can establish that the warnings given by NPC were inadequate.

NPC asserts that plaintiff cannot satisfy her ultimate burden of proving proximate causation because Mr. Ingram's prescribing oncologist, Dr. Khader Hussein, has testified that he would not have changed his course of treatment and would have prescribed Aredia even if he had been adequately warned. Dr. Hussein's sworn deposition testimony, given on March 18, 2011, is as follows:

> Q. And if you had known that Aredia had that potential complication [ONJ], would you have prescribed it for Mr. Ingram anyway?
>
> A. Yes.

Deposition of Dr. Hussein, Doc. No. 81-32, p. 49.

The court finds that this testimony is sufficient under Eck to rebut the above-described rebuttable presumption that arises under Oklahoma's learned

intermediary doctrine. Dr. Hussein testified that had he known of Aredia's potential complication of osteonecrosis of the jaw, he would have prescribed it for Mr. Ingram anyway. This testimony establishes that although the prescribing physician, Dr. Hussein, would have read and heeded the warnings regarding Aredia and ONJ, this would not have changed Dr. Hussein's decision to prescribe it to Mr. Ingram. *See* Eck, 256 F.3d at 1019 (*citing* Woulfe v. Eli Lily & Co., 965 F. Supp. 1478, 1485 (E.D. Okla. 1997)). Based on Dr. Hussein's unequivocal and undisputed testimony, the "burden shifts rather heavily back upon" the plaintiff to either "discredit the physicians' testimony or call into question the substance of the testimony, or otherwise demonstrate that the alleged failure to warn was the proximate cause" of Mr. Ingram's injuries. Eck, 256 F. 3d at 1019.

Here, plaintiff has not discredited Dr. Hussein's testimony, nor has she called into question the substance of his testimony. In an apparent attempt to "otherwise demonstrate" that the failure to warn was the proximate cause of Mr. Ingram's injuries, plaintiff has pointed out that Dr. Hussein additionally testified at his deposition that his prescribing practices for bisphosphonates have changed over time. These changes are: (1) he advises his patients to have a dental exam before starting treatment (Deposition of Dr. Hussein, Doc. No. 94-13, pp. 48-49); (2) he advises his patients to have any dental issues resolved before starting the drug (Doc. No. 94-13, pp. 48-49); (3) he advises his patients to tell their dentist or oral healthcare provider they are receiving the drugs (Doc. No. 94-13, p. 46); (4)

he advises his patients to avoid dental manipulations (Doc. No. 94-13, p. 46); and (5) when a problem develops the drug is generally stopped (Doc. No. 94-13, pp. 46-47). Plaintiff argues that:

> It is undisputed that [Mr. Ingram] did not have a dental exam between May, 2001 and January, 2003. He was not told to have his dental issues resolved before starting either Aredia or Zometa. He was not told to advise Dr. Harlan that he was receiving Aredia or Zometa at the time tooth #31 was extracted. He was not told to avoid dental manipulations such as the extraction of tooth #31 performed by Dr. Harlan. Finally, the drugs were not stopped when he began having problems in the area of tooth #30 or #31.

Plaintiff asserts that her summarization of this "evidence" demonstrates an issue of fact as to whether NPC's breach of duty proximately caused Mr. Ingram's jaw injury. In the context of the undisputed summary judgment evidence and the factual record of Mr. Ingram's dental care history, however, these mere arguments are insufficient at the summary judgment stage to demonstrate how the changed practices would have prevented injury to Mr. Ingram or how his injury would have been avoided had the new prescribing practices identified by Dr. Hussein been implemented in Mr. Ingram's case.

In determining whether plaintiff has established that the noted changes in Dr. Hussein's prescribing practices would have prevented Mr. Ingram's jaw injuries, the court finds that, based on the undisputed summary judgment evidence, the appropriate date for considering NPC's duty to warn is January of 1999, when Mr. Ingram was prescribed Aredia by Dr. Hussein. The court notes

that plaintiff's expert, Dr. Robert Marx, has testified in this case that Mr. Ingram already had ONJ when he began taking Zometa in January of 2003. Deposition of Dr. Marx, Doc. No. 101-1, p. 51. Dr. Marx testified that Mr. Ingram's case "seems to be related to Aredia" and that the Zometa in 2003 "just perpetuated the osteonecrosis of the jaw in this case." Id. Since any NPC warning concerning ONJ when Mr. Ingram was changed over to Zometa would not have prevented ONJ, the adequacy of NPC's warnings at that time, *i.e.*, January of 2003, is not relevant. When this finding is kept in mind, it is clear that plaintiff's arguments regarding Dr. Hussein's changed prescribing practices are insufficient to discharge her burden of proof on proximate causation. As demonstrated above, Dr. Hussein has unequivocally testified that had he known in January of 1999 that Aredia had the potential complication of ONJ, he would have prescribed it for Mr. Ingram anyway.

Additionally, the court notes that plaintiff's expert Dr. Marx has testified at his deposition in this case that he does not believe that the extraction of tooth #30[1] triggered the development of ONJ in Mr. Ingram (Doc. No. 101-1, pp. 40-41); that by the time of the extraction of tooth #31 in 2003, Mr. Ingram had already had osteonecrosis of the jaw for well over two years (Doc. No. 101-1, p. 46); and that Dr. Marx himself did not recommend that Mr. Ingram stop taking

[1] Tooth #30 was extracted in January of 1998. NPC's Statement of Undisputed Facts, Doc. No. 81, paragraph 33. This fact was not controverted by plaintiff.

Zometa in February of 2004, agreeing that there is no compelling reason to discontinue the medication if it provides an oncological value for the patient. (Doc. No. 101-1, pp. 60-61).[2]

The court concludes that plaintiff has failed to meet her burden of proof on the issue of proximate cause, a burden which the Tenth Circuit has explained in Eck shifts "rather heavily" back upon plaintiff, not NPC or the court. Plaintiff has not demonstrated, by reference to evidence in the summary judgment record, that any of the changed prescribing practices described by Dr. Hussein would have prevented Mr. Ingram's injury. This conclusion is based on the undisputed timeline of events concerning Mr. Ingram's oncological and dental care, the lack of any evidence that the changed prescribing practices would have prevented Mr. Ingram's injury, and plaintiff's failure to point to specific summary judgment evidence to create a genuine issue of fact as to whether NPC's failure to warn was the proximate cause of Mr. Ingram's injury.

NPC is also entitled to summary judgment on plaintiff's claim for wrongful death. A review of plaintiff's Complaint, Doc. No. 1, reveals that it contains two counts, neither of which is wrongful death. Thus, it appears that plaintiff has failed to state a claim for wrongful death. Even were the court to assume for the

[2] The court cites the deposition testimony of plaintiff's expert Dr. Marx for the limited purpose of considering whether plaintiff's response is sufficient to discharge her burden of proof on proximate causation at this stage of the proceedings. In light of the court's summary judgment rulings on the failure to warn, the court does not find it necessary to separately rule on NPC's Motion to Exclude Certain Testimony of Plaintiff's Expert Dr. Robert Marx, filed concurrently with its Motion for Summary Judgment.

sake of argument that a wrongful death claim exists given other allegations in the Complaint, such a claim cannot withstand summary judgment. NPC argues that it is entitled to summary judgment on the wrongful death claim because plaintiff has failed to present expert testimony establishing that NPC's product caused Mr. Ingram's death.

Plaintiff's response makes reference to the following deposition testimony given by Mr. Ingram's oncologist, Dr. Hussein, after defense counsel inquired into the cause of Mr. Ingram's death:

> Q. And ultimately Mr. Ingram expired?
>
> A. That's correct.
>
> Q. And under causes of death, you listed as the number one cause, multiple myeloma?
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> A. That's correct.
>
> Q. And then secondary was pancytopenia?
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> A. Pancytopenia, yes.
>
> Q. And clostridium colitis?
>
> A. Yes.
>
> Q. Would you describe each one of those for us as to what those conditions are?
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> A. Multiple Myeloma is a cancer of the marrow of the bone characterized by bone lesions, anemia, increased proteins in the blood, kidney failure, proteins in the urine, high blood calcium. These are the main problems with the disease. It's also a disease that impairs the immune system and causes people to have infections. It makes them susceptible to infections.

> Pancytopenia is – – it means a low white blood count, low platelet count, low red blood count combined. It is caused either by myeloma itself, replacing the marrow, or the chemotherapy effect. Low white count causes infections, low red count causes weakness and shortness of breath, low platelets causes bleeding.
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> Clostridium colitis is a form of infectious inflammation of the colon caused by a bacteria called clostridium difficile, which is quite often seen in people who are receiving broad spectrum antibiotics, and people with impaired immune systems are susceptible to it. That's it. Nutshell description.

Deposition of Dr. Hussein, Doc. No. 94-13, pp. 41-43.

Relying only on the deposition testimony of Dr. Hussein set forth above, plaintiff states in a conclusory fashion that "Mr. Ingram had been on long-term broad spectrum antibiotics as a result of his ONJ[,]" and that "[t]his evidence is sufficient to create a jury issue on the wrongful death claim." However, the cited testimony of Dr. Hussein does not provide sufficient evidentiary support at the summary judgment stage for plaintiff's contention that Mr. Ingram "had been on long-term broad spectrum antibiotics as a result of his ONJ." Indeed, the cited testimony of Dr. Hussein does not specifically tie the broad spectrum antibiotics Mr. Ingram may have received to ONJ or any NPC product. This is clearly a case where the causes of Mr. Ingram's medical conditions and death cannot be determined absent expert testimony. *See* Christian v. Gray, 65 P.3d 591, 601-02 (Okla. 2003) ("When an injury is of a nature requiring a skilled and professional

person to determine cause and the extent thereof, the scientific question presented must necessarily be determined by testimony of skilled and professional persons.") Plaintiff has come forward with no such expert testimony at the summary judgment stage to support her theory of liability under the purported wrongful death claim against NPC. Therefore, NPC is entitled to summary judgment on plaintiff's claim for wrongful death.

Plaintiff has failed to demonstrate that there is a genuine dispute for trial. Accordingly, summary judgment in favor of NPC on all claims is appropriate. Therefore, for the reasons stated above, Novartis Pharmaceuticals Corporation's Motion for Summary Judgment **[Doc. No. 81]** should be and is hereby **GRANTED.** Judgment will issue on a separate document in accordance with the Federal Rules of Civil Procedure.

It is so ordered this 18th day of July, 2012.

Tim Leonard

TIM LEONARD
United States District Judge